REMARKS

Claims 26-35 are pending. Claims 26 and 35 have been amended and claims 1-8 and 24 have been canceled without prejudice as drawn to a non-elected invention. No new matter has been added.

Initially, Applicants acknowledge with appreciation that the Examiner has withdrawn the previous objection under 35 U.S.C. § 112, first paragraph, on the ground that the specification does not reasonably provide enablement for the term "organic non-peptide compound."

The Examiner has made the restriction requirement final and requires Applicants "to cancel the non-elected claims and non-elected subject matter from the instant claims or define the 'organic non-peptide compounds' with the elected formula of the Group I compounds." The Examiner further states that "Claims 26-35 are only being examined as they read on the formula of Group I compounds for treating cancer. Applicants are required to limit the instant claims to the formula of Group I compounds."

In response, Applicants have canceled Claims 1-8 and 24 as drawn to a non-elected invention. However, the Examiner's requirement that Applicants limit the scope of Claims 26-35 to the formula Group I compounds is respectfully traversed.

Applicants' invention, as recited in Claims 26-35, is drawn to a *method* of treating cancer by, *inter alia*, administering to a patient an organic non-peptide compound that binds to one or more domains of a human protein of the p53 family under physiological conditions, and stabilizes a functional conformation of the protein. Claim 26 is a *generic* claim drawn to this invention. Claims 27-35 are method claims which depend from Claim 26. Claim 26-35 are not species claims that are drawn to a specific group of compounds.

Applicants respectfully submit that the Patent and Trademark Office ("PTO") has no statutory authority, nor any judicially created authority, to require Applicants to limit the scope of a generic claim, (i.e., claim 26) to a subgeneric concept defined by an examiner (i.e., a method of treating cancer by administering Group I compounds), and impose it upon Applicants. Nor does the PTO have any authority to restrict Applicants' claims as reading upon an arbitrarily defined concept. It is Applicants' right under 35 U.S.C. § 112 to set the metes and bounds of their invention as they see it. *In re Wolfram*, 179 USPQ 620, 622 (CCPA 1973).

The Office Action, by requiring Applicants to limit the scope of their claims to

Group I compounds, has inappropriately dissected Applicants' independent claim (claim 26) into multiple parts that Applicants are now deprived of their statutory rights under 35 U.S.C. § 112 to "claims particularly pointing out and distinctly claiming the subject matter which *Applicant regards as his invention.*" The Office Action has, in effect, carved out a portion of Applicants' invention, regarded that as Applicants' invention and rejected under the guise of a restriction requirement under 35 U.S.C. § 121. This the PTO cannot do. The courts have consistently ruled that any attempt by the PTO to reject a *single* claim (here, claim 26) as embracing more than one invention under 35 U.S.C. § 121 violates the basic right of an applicant to claim his invention as he chooses. *In re Weber*, 198 USPQ 328, 331-32 (CCPA 1978); *In re Haas*, 198 USPQ 334, 336 (CCPA 1978); *see also In re Watkinson*, 14 USPQ2d 1407, 1409 (Fed. Cir. 1990).

Moreover, since Claim 26 is a generic claim and there are no species claim drawn to particular compounds, the election of species requirement is clearly mooted. 37 C.F.R. § 1.146 expressly states that an examiner may require an election of species only in "an application containing a generic claim to a generic invention (genus) *and* claims to more than one patently distinct species embraced thereby." (Emphasis added.) Here, Applicants have canceled without prejudice species claims drawn to particular compounds (e.g., claim 24). Thus, the Examiner's election of species requirement is no longer applicable.

Furthermore, even assuming, *arguendo*, that there are species claims pending, once a generic claim has been found allowable, claims directed to species, which were withdrawn from consideration, but depend from or otherwise include all of the limitations of the allowed generic claim, should no longer be withdrawn from consideration and be found allowable. As MPEP § 806.04(d) states,

> [o]nce a claim that is determined to be generic is allowed, *all of the claims drawn to species in addition to the elected species which include all the limitations of the generic claim will ordinarily be obviously allowable in view of the allowance of the generic claim*, since additional species will depend thereon or otherwise include all of the limitations thereof.

(Emphasis added.) *See also* MPEP § 809.02(c), Examiner's Note.

Here, none of the claims stands rejected over any prior art. Further, as will be discussed below, Claim 26, the generic claim, is now in condition for allowance in light of the amendments, which obviated the Examiner's Section 112 objections. Accordingly, Claim 26 and all claims depend therefrom should now be allowed, and the Examiner's

requirement that Claims 26-35 be carved so that they are limited to Group I compounds should be withdrawn.

Claims 26-35 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite on the ground that the amount of the organic compound non-peptide compound used should be recited. In response, Claim 26 has been amended to recited that an "effective amount" of the organic non-peptide compound is administered. Applicants respectfully submit that this amendment obviates the rejection.

Claims 26-35 stand rejected under 35 U.S.C. § 112, first paragraph, on the ground that the specification "does not reasonably provide enablement for the term 'cancer.'" The Examiner states that "changing the term 'cancer' to 'a cancer disease state is associated with possession of a mutant protein of the p. 53 family' would overcome this rejection." This rejection is respectfully traversed.

As discussed in detail in Applicants' Reply dated October 28, 2002, the specification provides ample guidance to one having ordinary skill in the art to practice the claimed method of treating cancer without undue experimentation. Further, the PTO has consistently issued patents with claims to methods of treating "cancer." Nevertheless, to expedite prosecution of this case, Claim 26 has been amended to recite "[a] method of treating a human patient for cancer that can be treated by increasing the activity of one or more proteins of the p53 family in cells affected by said cancer, comprising the steps of: (a) administering to said patient an effective amount of an organic non-peptide compound that binds, in said cells, to one or more domains of one or more of the patient's proteins of the p53 family, and stabilizes a functional conformation of said proteins under physiological conditions, and (b) permitting said stabilized protein to interact with one or more macromolecules that participate in a wild-type activity of said protein." Applicants respectfully submit that this amendment obviates the Examiner's rejection under 35 U.S.C. § 112, first paragraph. Support for this amendment may be found, for example, in the specification at pages 9-10 and 12; see also Claim 35.

With regard to the Examiner's suggested claim amendment, Applicants respectfully submit that it would unnecessarily limit the scope of the invention to treating cancer associated with mutant protein of the p53 family. The specification clearly discloses that present invention applies to both mutant and non-mutant p53 family proteins. (*See, e.g.*, page 12, lines 20-30; page 13, lines 11-29; page 14, lines 10-15.) Applicants respectfully submit that the present amendment reciting "cancer that can be treated by increasing the activity of one or more proteins of the p53 family in cells affected by said cancer,

comprising the steps of: (a) administering to said patient an effective amount of an organic non-peptide compound that binds, in said cells, to one or more domains of one or more of the patient's proteins of the p53 family, and stabilizes a functional conformation of said proteins under physiological conditions, and (b) permitting said stabilized protein to interact with one or more macromolecules that participate in a wild-type activity of said protein" is supported by the specification and would obviate the Examiner's rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the instant application is now in condition for allowance.

Applicants respectfully request prompt consideration of the pending claims and early allowance of the application.

If the Examiner wishes to comment or discuss any aspect of this application or response, applicants' undersigned attorney invites the Examiner to call him at the telephone number provided below.

Respectfully submitted,

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